K 123424

Boston Scientific

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510(k) Summary of Safety and Effectiveness
Boston Scientific Corporation
MDU5 PLUS™ Sterile Bag

Submitted By:

Boston Scientific Corporation
47215 Lakeview Boulevard
Fremont, CA 94538

Contact Person:

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Date Prepared: November 6, 2012

Proprietary Name: MDU5 PLUS™ Sterile Bag

Common Name: Sterile Cover

Classification Name: Transducer, Ultrasonic, Diagnostic (accessory)

Device Classification/ Product Code: Class II, 21 CFR 892.1570 / ITX

Predicate Device:

The MDU5 PLUS™ Sterile bag is substantially equivalent to the following device:

Product	510(k)	Clearance Date
CIVCO Poly Ultrasound Transducer Cover	K970513	June 20, 1997

Description of the Device:

The MDU5 PLUS™ Sterile Bag is supplied to the user as a sterile device and is intended for single use only. The MDU5 PLUS™ Sterile Bag is intended to cover the motor drive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker. The product consists of a long, narrow bag made of low density polyethylene with one open end. There is a face plate with a covered opening that is attached to the Sterile Bag. Once the Sterile Bag is covering the motordrive unit, the face plate connects to the nose of the motordrive. The face plate

is uncovered when the operator is ready to insert the catheter into the motordrive. The bag has been designed to be large enough and flexible enough to cover the motordrive unit while not impeding the 10cm of travel required by the pull-back sled that the motordrive attaches to. The MDU5 PLUS™ Sterile Bag is sufficiently clear as to not impede viewing the motordrive display.

The MDU5 PLUS™ Sterile Bag is sold separately as a stand-alone product but is also included as an accessory in the package with each compatible catheter. The materials used in the design of the MDU5 PLUS™ Sterile Bag have been selected to be compatible with electron beam sterilization (e-beam sterilization). The MDU5 PLUS™ Sterile Bag is folded and packaged in a Tyvek/Nylon or equivalent medical device packaging that is suitable for E-Beam sterilization.

Intended Use / Indications for Use:

The MDU5 PLUS Sterile Bag is intended to cover the motor drive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

Device Technology Characteristics and Comparison to Predicate Device:

The Intended Uses for both the MDU5 PLUS™ Sterile Bag and the predicate sterile cover are similar. The MDU5 PLUS™ Sterile Bag is a sterile cover, which is placed over the motordrive unit during ultrasound procedures in order to maintain the sterile field within the catheter lab. The predicate device is also used as a sterile transducer cover, also used to maintain the sterile field during ultrasound procedures. The MDU5 PLUS™ sterile bag is a long, narrow bag made of low-density polyethylene (LDPE), with one closed end and one open end that fits over the motordrive unit and attaches, via a faceplate, to the nose of the motordrive unit. The predicate sterile cover is also made of LDPE and is the same shape as the MDU5 PLUS™ sterile bag, with similar dimensions. The predicate device is also installed over the motordrive unit in a similar fashion, using a ring-type faceplate to attach to the nose of the motordrive. MDU5 PLUS™ sterile bag is sold as a sterile device to the end user as is the predicate device. Both the predicate device and the MDU5 PLUS™ sterile bag can be supplied as a stand-alone device as well as packaged as an accessory to compatible catheters.

In establishing substantial equivalence to the predicate device, Boston Scientific compared the material, design specifications and indications for use of the subject and predicate devices previously cleared in K970513 (cleared June 20, 1997). Additionally, performance testing has been completed for the subject device. The performance testing and device comparison demonstrate that the subject device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

Refer to the Predicate Device Comparison Table, located in Section IV, Proposed and Predicate Device Comparison.

Non-Clinical Data

Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical data includes Bench/Performance, Sterilization, Microbiology and Packaging tests, which were conducted on the subject device.

Bench/Performance Testing:
Bench testing was conducted to evaluate the physical integrity and functionality of the MDU5 PLUS™ Sterile Bag at T=0 and T=13mo AA. Test criteria includes liquid barrier evaluation, pathogen penetration resistance and resistance to penetration by synthetic blood, resistance to common cleaning agents, seal strength, label/sticker orientation and durability, interface and compatibility with ancillary devices, user interface requirements and environmental requirements.

Sterilization Validation:
Sterilization studies (including Bioburden) were conducted for the MDU5 PLUS™ Sterile Bag according to ISO 11137-2:2012.

Packaging Validation
The integrity of the packaging configuration was tested in accordance with ISO 11607-1 and ISO 11607-2. Testing was conducted on fully packaged units after being subjected to electron beam sterilization, climactic conditioning, and distribution challenge conditioning. Test criteria included visual inspections, sterile barrier integrity and sterile barrier seal strength.

Clinical Data

No clinical or animal data are included in this submission.

Conclusion

The MDU5 PLUS™ Sterile Bag is substantially equivalent to the predicate CIVCO Sterile cover (K970513). The MDU5 PLUS™ test results support the determination of substantial equivalence to the predicate device, and confirm the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 20, 2013

Boston Scientific Corporation
c/o Ms. Lori R. Smith
Sr. Regulatory Affairs Specialist
47215 Lakeview Boulevard
Fremont, CA 94538

Re: K123424
Trade/Device Name: MDU5 PLUS Sterile Bag
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: November 6, 2012
Received: November 30, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123424

Device Name: MDU5 PLUS Sterile Bag

Indications for Use:

The MDU5 PLUS Sterile Bag is intended to cover the motordrive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health